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Guidance for the Reregistration of Pesticide Products Containing Fenthion as the Active Ingredient

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Guidance for the Reregistration of Pesticide Products Containing FENTHION as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
FENTHION
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 55-38-9
OPP CHEMICAL NO. 053301

EPA CASE NUMBER GS0290
JUNE 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI:	Acceptable Daily Intake
a.i.:	active ingredient
CAS:	Chemical Abstract Services (number)
CSF:	Confidential Statement of Formula
EC_{50}:	Median Effective Concentration - the concentration of substance producing a specific effect or response in 50 percent of the test organisms.
EEC:	Estimated Environmental Concentration - an estimate of the concentration of a pesticide occurring in or on various media (i.e., soil, water, vegetation) after pesticide application.
EPA:	The U.S. Environmental Protection Agency (Agency)
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
LC_{50}:	Median Lethal Concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).
LD_{50}:	Median Lethal Dose - a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).
LEL:	Lowest Effect Level
MPI:	Maximum Permissible Intake
MRID:	Master Record Identification (number) - EPA's system of tracking studies used in support of registration.
NPDES:	National Pollution Discharge Elimination System
NOEL:	No Observed Effect Level
OPP:	The Office of Pesticide Programs of the U.S. EPA

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and use index are available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 or from the Order Desk (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV-Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C. of Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common Name: Fenthion

Chemical Name: 0,0-dimethyl-0-[4-(methylthio)-m-tolyl] phosphorothioate.

Other Chemical Names: 0,0-dimethyl-0-[3-methyl-4-(methylthio) phenyl] phosphorothioate

0,0-dimethyl-0-4-methylthio-m-tolyl phosphorothioate

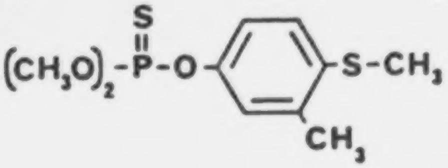
Trade Names: Baytex; Entex; Bayer 29493; Bayer S-1752; Baycid; Lebaycid; Spotton; Tiguvon; Mercaptophos

Chemical Class: Organophosphate

Empirical Formula: $C_{10}H_{15}O_3PS_2$

Molecular Weight: 278.3

Molecular Structure:



CAS Registry No.: 55-38-9

AI_3 Registry No.: 25-540

OPP Chemical No.: 053301

Year of Initial Registration: 1965

U.S. and Foreign Producers: Mobay Chemical Corp (United States); and Bayer AG (Federal Republic of Germany).

Physical/chemical properties of fenthion.[2]

Color: Yellow-tan

Physical State: Liquid

Odor: Slight garlic odor

Melting Point: <-25°C

Boiling Point: 105°C at 0.01 mm Hg

Density: 1.250 at 20°C

Solubility: Practically insoluble in water (55 mg/l), soluble in methanol, ethanol, ether, acetone, and many other organic solvents (especially chlorinated hydrocarbons)

Vapor Pressure: 3×10^{-5} mm Hg at 20°C

Refractive Index: N_D^{20} 1.5698

Stability: Stable up to 210°C, resistant to alkali up to pH 9.0

B. Use Profile

Fenthion is a contact and systemic organophosphate insecticide/acaricide registered for mosquito and insect control on swamps, standing water, recreation areas, alfalfa, pasture grass, forests, barns, poultry houses, nonfood areas of commercial buildings and restaurants, and homes; for lice control on cattle (beef and non-lactating dairy) and hogs; for control of ants, mites, leafhoppers, and aphids on ornamentals and flowers; for bird control; and for use on rice to control mosquitoes (in the State of California only).

Over half of the fenthion used in the United States is for mosquito control. A substantial portion of the remainder is used for control of pests on cattle with lesser amounts used on swine and bird control. Minor use sites include pest control in homes, buildings, food-handling establishments, ornamentals, and forest tree.

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[2] The physical/chemical properties of fenthion listed in this section were obtained from Merck Index, 10th Edition.

Fenthion is marketed as 1% dust (D) formulations; 2, 4, 7, and 9.67 pound (lb) active ingredient (ai) per gallon (gal) emulsifiable concentrate formulations (EC); 2, and 4, lb/gal soluble concentrate/liquid (SC/L) formulations; 1, 2, and 5 percent granular (G) formulations; and liquid-ready to use (L-RTU) formulations ranging from 0.5 to 20 percent active ingredient. Both ground and aerial applications are used to control mosquitoes and control measures are directed to both the aquatic (larval/pupal) stages and the free-flying adult stage.

There are 51 federally registered [FIFRA Section 3] products (3 technical, and 48 end-use) and 20 Special Local Need [FIFRA Section 24c)] registrations containing fenthion as a single active ingredient. There are also 13 federally registered end-use products (2 formulation intermediates and 11 end-use) containing fenthion in combination with one or more other active ingredients. There are 6 intrastate registrations containing fenthion as an active ingredient.

III. AGENCY ASSESSMENT

A. INTRODUCTION

The Agency's preparation of this Fenthion Registration Standard included a review of all data submitted, in support of the registration of fenthion, through September 1986.[3] At the conclusion of that review, the Agency identified those data still needed to fully evaluate the human, environmental, and ecological risks associated with the use of fenthion. Registrants with products containing fenthion must develop and submit those data to the Agency in order to maintain their current registrations or to register new products containing fenthion. A summary of those data gaps may be found in Appendix I of this document. The Agency's assessment of the available data relating to human, environmental, and ecological effects is set forth below.

B. PRELIMINARY HEALTH RISK ASSESSMENT

1. Acute Toxicity

Based on the results of acceptable acute toxicity studies, fenthion is considered to be in toxicity Category II (moderately toxic) for acute oral toxicity (rat LD_{50} = 295.6 ± 17.2 mg/kg (females) and 250.2 + 8.6 mg/kg (males)), acute dermal toxicity (rat LD_{50} = 2830 mg/kg bw (females) and 1680 mg/kg bw (males)), and acute inhalation toxicity (rat LC_{50} = approximately 0.8 mg/liter (females) and 1.2 mg/liter (males)); and Toxicity Category IV (minimally toxic) for eye irritation (rabbit) and dermal irritation (rabbit - primary irritation index = 0.4). The dermal sensitization and acute delayed neurotoxicity potential of fenthion cannot be determined at this time.

2. Subchronic Toxicity

Two supplementary subchronic feeding studies for the dog and rat, and one supplementary subchronic dermal study for the rabbit were reviewed. In the dog subchronic feeding study significant inhibition of serum cholinesterase in the 5 and 50 ppm groups and markedly reduced erythrocyte cholinesterase activity in the 50 ppm group was reported. In a similar study in rats, inhibition of cholinesterase activity in both the males and females at the 25 and 100 ppm levels was reported. In the rabbit subchronic dermal study, New Zealand white rabbits were dosed dermally with fenthion on a daily basis for 3 weeks. The study reported a plasma and red blood cell cholinesterase no observed effect level (NOEL) of <5 mg/kg/day (the lowest dose tested) and a systemic NOEL >25 mg/kg/day (the highest dose tested). However, because these studies were unacceptable for filling this data requirement, the submission of acceptable subchronic toxicity studies is required.

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[3] Data submitted in response to the Agency's Data Call-In Letter of April 29, 1986 were not received in time to be included in the data base reviewed for this Standard. Data submitted in response to the April 29, 1986 Data Call-In are currently in various stages of the Agency's review process. Due dates for data still outstanding from the April 29, 1986 Data Call-In are indicated on the data requirement tables as specific calendar dates. All data submitted in support of the registration of fenthion since September 1986 will be evaluated when the Agency updates this Registration Standard.

3. Chronic Toxicity

Chronic feeding studies involving the dog and the rat were reviewed and are considered to be inadequate. In a chronic feeding study male and female Beagle dogs were fed from 0 to 60 ppm fenthion over two years. A cholinesterase inhibition NOEL of 3 ppm was reported. In a similar study in Wistar rats the cholinesterase inhibition NOEL was 3 ppm and the systemic NOEL was 15 ppm. However, because these studies were unacceptable for filling this data requirement, the submission of acceptable rodent and nonrodent studies is required.

4. Ocular Effects (Toxic Effects on the Eye)

Organophosphate pesticides, such as fenthion, have been observed to produce toxic effects on the eye. Extensive human poisoning produced a syndrome of effects on vision ranging in severity from myopia to congestion or atrophy of the optic nerve. Studies on dogs and rats utilizing organophosphate pesticides, including fenthion, duplicated the effects observed in humans.

Based on this information and the lack of specific attention to the pathology of the eye in the available studies, the Agency is requiring the submission of special studies, in rodent and nonrodent species, on the effects of fenthion on the eye.

5. Oncogenicity

At this time the Agency has classified fenthion as an "Inadequate evidence, Group D" carcinogen based on the review of two supplementary oncogenicity studies for the rat and one supplementary oncogenicity study for the mouse. In the first rat study groups of 50 male and 50 female Fisher 344 rats were fed fenthion in their diets at doses of 10 and 20 ppm for 103 weeks. Another group of 25 male and 25 female Fisher 344 rats were fed diets containing 0 ppm of fenthion for 103 weeks. This study provided insufficient evidence for the oncogenic potential of fenthion because of the low doses used; the number of controls; and the lack of a demonstrated toxic response. In the rat study groups of 50 male and 50 female SPF (Wistar strain) rats were fed diets containing fenthion at nominal doses of 3, 15, and 75 ppm, respectively, for 24 months. No oncogenic effect was evident in SPF (Wistar strain) rats in this 2-year dietary study. However, there is no assurance that the treated rats actually consumed the intended amounts of fenthion,since no individual animal food consumption data were provided. There was also no indication that the feed mixtures were analyzed and monitored on a scheduled basis for reproducibility and stability.

In the mouse oncogenicity study 50 male and 50 female B6C3F1 mice were fed fenthion in their diets at doses of 10 and 20 ppm for 103 weeks. Histopathologic findings revealed a higher incidence of several types of sarcomas of the skin and subcutaneous tissue in treated male B6C3F1 mice that appeared to be associated with the administration of fenthion and suggested that fenthion was oncogenic in this sex and strain of mice. However, this study provides insufficient evidence for the oncogenic potential of fenthion because of the low doses used; the number of controls; and the lack of a measured toxic response. No acceptable data are available on the oncogenic potential of fenthion. Oncogenicity studies are required in two species.

6. Developmental Effects (Teratogenicity)

The Agency reviewed teratology studies for the rat and rabbit, but only the rabbit study was found to be acceptable. Because of the deficiencies in the rat study, the Agency is requiring the submission of a new acceptable teratology study in a second species (preferably the rat) or submission of the following information to update the existing rat study:

1) An English translation of the study "Machemer, L. and E.G. Stenger. Zur Beurteilung der Foeten im teratollogischen Experiment. Modifikation der "Wilson-Teechnik". Arzneim. Forsch. (Drug Reseach) 21:144-145, 1971.";

2) An English translation of the dam and litter data for the study; and

3) An English translation of the historical control data for incidences of malformations for the FB 30 rats as supplied by Bayer AG, Zentralstelle für Versuchstiere.

In the rabbit teratology study, female and male Chinchilla hybrid rabbits were mated in a 1:1 ratio twice, if possible, by the same male as soon as possible after the initial mating. Mated females were randomly assigned to 4 groups of 20 each and were administered, orally by gavage from days 6 through 18 of gestation, the following doses of fenthion: vehicle control (0); 2, 6 and 18 mg/kg/bw respectively. In this study the maternal toxicity NOEL was 6 mg/kg/day; the fetotoxic NOEL was 2 mg/kg/day; and the teratogenic NOEL was >18 mg/kg/day. The Agency concluded that fenthion does not induce developmental effects in rabbits.

7. Reproductive effects

A supplementary reproduction study in the rat has been reviewed. In this study groups of 10 male and 10 female FB_{30} (stock Elberfeld) rats were fed doses of either 0, 3, 15, or 75 ppm fenthion in their feed for 3 generations. The study reported that chronic ingestion of fenthion by rats in doses up to 75 ppm in feed over 3 generations did not appear to have any adverse effects on reproduction. However, the Agency cannot perform an adequate toxicological evaluation of the study without the raw data set forth below. Therefore, either the raw data from the existing study must be submitted to remedy its deficiencies or a new multi-generation reproductive study is required.

The following specific data must be submitted in order for the Agency to evaluate this existing study:

1) information on individual dams;

2) information on individual litters per dose level;

3) information on individual pups;

4) number of pups per litter for individual dams at each dose level;

5) number of litters per dose level;

6) food consumption;

7) individual body weights for parents and progeny in each generation; and

8) the pathology report is incomplete and has insufficient detail.

8. Mutagenicity

The Agency has acceptable gene mutation, structural chromosomal aberrations, and other genotoxic effects data for fenthion. Based on the results of the structural chromosomal aberrations study the Agency concludes that fenthion is non-mutagenic in male mice up to 25 mg/kg bw (the highest dose tested); is moderately toxic at 25 mg/kg bw; and that the systemic NOEL for mutagenicity is 10 mg/kg bw. Fenthion produced no mutagenic effects in either the gene mutation test or the other genotoxic effects test. No additional mutagenicity tests are required.

C. ECOLOGICAL EFFECTS

The available studies show that fenthion is extremely hazardous, especially to birds and aquatic invertebrates. However, these studies do not provide sufficient information to quantify or evaluate ecological hazard. A discussion of the available ecological effects information is set forth below.

1. Terrestrial Organisms

Fenthion is very highly toxic to birds as demonstrated by both acute and dietary studies. Acute oral tests with mallards, bobwhite quail, and doves resulted in LD_{50}'s of 5.94 mg/kg, $\underline{<}$ 4 mg/kg, and 2.5 mg/kg, respectively. Dietary studies (8 days) with bobwhite and mallards resulted in LC_{50}'s of 30 ppm and 231 ppm, respectively. The potential for secondary toxicity was demonstrated when kestrels were fed, and subsequently died from, house sparrows that had been killed by an oral dose of 10 mg/kg fenthion. Field studies and incident reports demonstrate that when used as directed for mosquito and fly control, cattle treatment, and as a bird perch avicide, fenthion will cause nontarget avian, and possibly mammalian, mortality. Birds and mammals were found dead following an application of fenthion at 0.04 to 0.05 lb. ai/A. Thus there is evidence that when fenthion is applied even at rates as low as 0.05 lb. ai/A, bird, and possibly mammal mortality will occur.

2. Aquatic Organisms

Available acute test results indicate that fenthion is moderately to highly toxic to fish. Acute tests with fathead minnows and striped bass resulted in LC_{50}'s of 3.2 ppm and 0.453 ppm, respectively. Fenthion is very highly toxic to aquatic invertebrates (48-hour LC_{50}'s of 0.62 ppb and 0.80 ppb for *Simocephalus* (Daphnid) and *Daphnia pulex*, respectively), shrimp (96-hour LC_{50} of 0.11 and a 24-hour LC_{50} of less than 0.066 ppb for pink shrimp), and mollusks (EC_{50} of 340 ppb).

Fenthion is moderately toxic to estuarine fish with a 96-hour LC_{50} of 1.6 ppm to striped mullet. Wild caught tadpoles (Rana catesbeiana) were not killed after 96 hours exposure to 5 ppm fenthion, thus indicating that fenthion is no more than slightly toxic to amphibians. Aquatic field testing has shown the use of fenthion to control mosquitoes may kill fish and blue crabs. Field tests have also shown that certain aquatic invertebrates such as amphipods and isopods, will be killed when fenthion is applied directly to water at 0.1 lb. ai/A, and that shrimp will be killed when fenthion is applied directly to water at 0.03 and 0.01 lb. ai/A.

3. Endangered Species

There are sufficient data to indicate that the currently registered uses of fenthion may affect endangered species.

Because of its demonstrated toxicity to nontarget species and its intended use pattern, fenthion has been identified by the U.S. Fish and Wildlife Service (FWS), as being likely to jeopardize endangered species when used to control or eradicate mosquito larvae, when used on livestock and as an avicide. Based on this determination, FWS specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with the FWS to develop labeling intended to reduce or eliminate hazard to endangered species.

4. Non-target Insects

Data from honey bee acute contact toxicity studies indicate that fenthion is highly toxic to honey bees (contact LD_{50} = 0.308 ug/bee), when bees are exposed to direct treatment. The requirement for a honey bee acute contact study is fulfilled. However, because the acute data indicate high toxicity, a study to characterize the toxicity of fenthion residues on foliage is required.

D. ENVIRONMENTAL PROFILE

Available data are insufficient to fully assess the environmental fate of fenthion.

1. Degradation

Under aerobic conditions, ^{14}C fenthion, at 1 ppm, degraded with a half-life of <1 day in nonsterile silt loam soil in the dark at 75% moisture and room temperature. The major nonvolatile degradates were fenthion sulfoxide, 3-methyl-4-(methylsulfonyl) phenol, and 3-methyl-4-(methylsulfinyl) phenol. Fenthion sulfone and 3-methyl-4-(methylsulfony)anisole were also identified. After 59 days, 3-methyl-4-(methylsulfonyl) phenol and 3-methyl-4-(methylsulfony)anisole were the major soil residues. In sterilized soil, ^{14}C fenthion degraded with a half-life of 14-21 days; degradates included fenthion sulfoxide and 3-methyl-4-(methylsulfiny)phenol.

Under anaerobic conditions, fenthion, at 0.2 ppm, degraded from 1.9% to 1.0% in silt loam soil after 60 days incubation. The major nonvolatile degradate was 3-methyl-4-(methylsulfonyl)phenol. Fenthion sulfoxide, fenthion sulfone, 3-methyl-4-(methylsulfiny)phenol and 3-methyl-4-(methylsulfony) anisole were also isolated.

Aged ^{14}C fenthion residues (uncharacterized) were mobile in a column of loam soil leached with 22.5 inches of water over a 45-day period. Fenthion sulfoxide, fenthion sulfone, P=O sulfoxide, fenthion phenol, 3-methyl-4-(methyl-sulfiny)phenol, and 3-methyl-4-(methylsulfony)phenol were identified in the leachate. The majority of the fenthion residues (uncharacterized) remained in the upper 4 centimeters of the soil column.

The bioconcentration factors for residues of fenthion, fenthion sulfone, and fenthion oxygen analog sulfone in carp exposed to 0.01 and 0.1 ppm fenthion were 2000x and 2300x, respectively. About 50% depuration occurred within 40 days. All possible degradates could not be determined since the test substance was not radiolabeled.

2. Ground Water

The Agency reviewed the fenthion literature for information pertaining to fenthion residues in drinking water, including ground water. No reports were found regarding fenthion residues in water. Therefore, the Agency is not proposing to regulate fenthion for drinking water at the present time. However, field dissipation studies with fenthion and monitoring for degradates,including 3-methyl-4-(methylsulfonyl) phenol and 3-methyl-4-(methylsulfinyl)phenol, are required. The Agency is also requesting leaching studies with fenthion and an aged leaching study for degradates. When the required data are submitted, the potential of fenthion and its degradates to contaminate ground water will be reassessed.

3. Reentry

Fenthion does not meet the acute toxicity criteria for requiring reentry data as set forth in 40 CFR section 158.390. However incident reports in the Agency's files, showing that persons treating animals with fenthion have experienced toxic effects, do meet the 40 CFR section 158.390 reentry data criteria. Fenthion also meets the exposure criteria of 40 CFR section 158.390 in that fenthion is registered for use on ornamentals and the agricultural practices for ornamentals include human tasks which involve substantial exposure to pesticide treated surfaces.

4. Spray Drift

There are no data available to assess the risks to nontarget organisms caused by drift from applications of fenthion. The Agency is requiring droplet size spectrum and spray drift field evaluation tests for fenthion due to the toxicity of the chemical, the methods of application (mist blower or cold fogger), and the likely exposure of off-site humans and wildlife to the pesticide. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of fenthion in various outdoor uses. The spray drift field evaluation is to be performed to reflect the application equipment use pattern, and typical locations of use (including different weather factors) in the application of fenthion.

E. TOLERANCE REASSESSMENT

Tolerances for residues of the insecticide fenthion in or on various raw agricultural commodities (RACs) are currently expressed in terms of fenthion and its cholinesterase inhibiting metabolites (40 CFR 180.214). The Agency has evaluated the residue and toxicology data supporting these tolerances and has determined that it does not have sufficient data to support the currently established tolerances for residues of fenthion. The Agency will make a more complete assessment of the established tolerances for fenthion after the required residue and toxicological data are submitted and evaluated.

1. Residue Data

The metabolism of fenthion in plants and animals is not adequately understood. Available plant metabolism data do not provide sufficient information regarding the determination of total residues in the treated crops, the distribution of residues in the plant, and the efficiency of the extraction procedures. Residues were not sufficiently identified in milk and tissues of livestock.

Data gaps exist for plant and animal metabolism and storage stability. On receipt of the data requested in these sections of the registration standard, the conclusions stated above regarding the adequacy of established tolerances are subject to change. Furthermore, since the data required for individual commodities are dependent on the metabolism data, the Agency recommends that metabolism data be obtained and submitted prior to any required residue data. The

Agency will not assess tolerances for residues in animal commodities until the requested animal metabolism studies are submitted and evaluated.

Adequate gas chromatographic/flame detection (GC/FD) methods are available for data collection and enforcement pertaining to residues of fenthion and its cholinesterase-inhibiting metabolites in or on various commodities. Gas chromatography/electron capture detector (GC/EC) methods are available for data collection and enforcement, although these procedures are very tedious and time-consuming.

The Codex Maximum Residue Limits (MRL) residue definition is expressed as the sum of fenthion, its oxygen analog, and their sulfoxides and sulfones, expressed as fenthion; the current U.S. Tolerance definition is expressed as residues of fenthion and its cholinesterase-inhibiting metabolites. Although these definitions are phrased somewhat differently, the Agency feels that they are equivalent. A decision regarding the potential for compatibility between the permanent Codex MRL and the U.S. tolerances for milk and fat, meat, meat by products of cattle and hogs will not be made until the adequacy of the U. S. tolerances have been ascertained. Codex MRLs have been established for residues of fenthion in rice, fat, meat, meat by products of cattle and hogs, and milk; Mexican tolerances have been established for residues of fenthion in or on rice, rice straw, alfalfa, and alfalfa hay; and Canadian tolerances have been established for fat, meat, meat by products of cattle, hogs, and sheep.

2. Toxicology Data

The available toxicity data are insufficient for the Agency to calculate an Acceptable Daily Intake (ADI) for fenthion and therefore the Maximum Permissible Intake (MPI) for a 60 kg human has not been determined.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

1. Special Review

The Agency is not initiating a special review for fenthion at this time.

Rationale: Although the Agency's review of ecological data shows that bird kills, due to the use of fenthion for mosquito control, for bird control, and for use on animals for insect control, have been reported, and that aquatic uses for mosquito control may cause adverse effects to fish and aquatic invertebrates, additional data are needed before the Agency can complete a full assessment of this hazard potential. Therefore, based on the review and evaluation of all available data and other relevant information on fenthion, the Agency has determined that a special review of fenthion is not supported by the available data at this time. However, the Agency is requiring additional data, i.e., an avian reproduction study, terrestrial and aquatic field testing. When those data have been received and evaluated EPA will determine if it should place the chemical in Special Review.

2. Restricted Use

The Agency is classifying all fenthion end-use products with directions for use on agricultural crops, ornamental plants and forest trees, uncultivated agricultural and non-agricultural outdoor areas, aquatic sites, livestock and bird roosting areas as Restricted Use pesticides, based on avian, fish and aquatic invertebrate toxicity. It is the Agency's position that affected products must bear appropriate restricted use labeling in order to remain in compliance with FIFRA.

Rationale: The uses of fenthion listed above exceeds restricted use criteria. According to 40 CFR 162.11 (c) a pesticide is a candidate for restricted use if exposure to the pesticide will exceed 1/5th the avian LC_{50} and 1/10th the acute LC_{50} for aquatic organisms, or if use causes more than minor or nondiscernible adverse effects. Furthermore, if application procedures require specialized training and/or expertise and if failure to follow the use directions in a minor way would result in more than minor or nondiscernible adverse effects, the pesticide may be restricted. Although incident data in the Agency's files are limited, the Agency believes that even a few reported incidents are considered significant since it is believed that most incidents go undetected or unreported. The incidents reported coupled with the high toxicity of fenthion to birds and aquatic organisms suggests that more than minor or non-discernible adverse effects could result from inadvertent misuse and/or misapplication. In addition, most of the uses for mosquito and bird control requires specialized training and equipment. Thus, the Agency is requiring that the uses of fenthion identified above be classified for restricted use in order to ensure that fenthion is applied efficiently and properly.

3. Reentry Requirements

The Agency is establishing an interim 24-hour reentry interval for the use of fenthion on ornamentals until adequate data have been submitted and evaluated.

Rationale: Fenthion is categorized as a Toxicity Category II pesticide by the dermal route. It is also a cholinesterase inhibitor. It is registered for use on ornamentals, the agricultural practices for which involve substantial hand labor and therefore substantial potential exposure to fenthion treated surfaces. The Agency believes that a 24-hour interim reentry interval is necessary to protect workers who may enter treated areas following application.

4. Groundwater Concerns

Groundwater and drinking water monitoring are not required for fenthion's major metabolites at this time.

Rationale: The Agency reviewed the fenthion literature for information pertaining to fenthion residues in drinking water, including groundwater. No reports were found regarding fenthion residues in water. The Agency is requesting field dissipation studies with fenthion, with monitoring for degradates, including 3-methyl-4-(methylsulfonyl)phenol and 3-methyl-4-(methylsulfinyl) phenol. The Agency is also requiring leaching studies with fenthion and an aged leaching study for degradates.

5. Protective Clothing

The Agency is requiring protective clothing for workers who mix, load or apply fenthion, dispose of fenthion products, repair contaminated mixing/loading and application equipment, or reenter treated areas before the 24-hour reentry interval has expired.

Rationale: Generally, protective clothing requirements for early reentry of workers into treated areas before the expiration of the reentry interval are based on the acute toxicity of the active ingredient. Fenthion is in acute Toxicity Category II. In addition, the National Institute of Occupational Safety and Health has evaluated cases of peripheral neuropathy among veterinarians and allied personnel in a veterinary medical clinic. These data suggest that fenthion may be implicated in the etiology of the cases (FR Notice 50, No. 23, 4913 issued Monday, February 4, 1985).

Therefore, based on the Toxicity Category of fenthion and implication of fenthion with peripheral neuropathy, the Agency has determined that the protective clothing requirements described in the "Required Labeling" section of this document are appropriate for workers who mix, load or apply fenthion, repair contaminated mixing/loading and application equipment, dispose of fenthion products, or need to reenter treated areas soon after application.

6. Special Ocular Effects Study

The Agency is requiring special studies, in rodent and nonrodent species, on the effects of fenthion on the eye.

Rationale: Organophosphate pesticides have been known to produce toxic effects on the eye, ranging in severity from myopia to congestion or atrophy of the optic nerve. Fenthion studies in the Agency's files lack specific attention to the pathology of the eye.

7. Tolerances and New Food Uses

The Agency will not issue any tolerances for significant new food uses[4].

Rationale: Until such time as reassessment of the present tolerances for fenthion is completed, the Agency will not issue tolerances for significant new food uses. The Agency needs additional residue and metabolism data in order to characterize the nature of residues in plants and animals. The Agency also needs specific toxicity data to calculate the Acceptable Daily Intake (ADI) to perform a tolerance reassessment. The Agency's calculated Theoretical Maximum Residue Contribution (TMRC) for fenthion, based on existing tolerances, is .0733 mg/kg.

8. Feed Additive Tolerance for Fenthion Residues in or on Rice Hulls

The Agency will propose a food additive tolerance for fenthion and its cholinesterase-inhibiting metabolites in rice hulls at 0.6 ppm. This will be done when tolerances for fenthion are next issued.

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[4] "New use" is defined in 40 CFR 152.3(p). In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

Rationale: There is currently no feed additive tolerance established for fenthion on rice hulls. Although residues did not concentrate in rice bran or milled rice processed from rice bearing measurable weathered residues they did concentrate in rice hulls by a factor of 3 to 6X.

9. Tolerance for Fenthion residues in or on Rangeland Grasses

A tolerance must be proposed for residues of fenthion in or on rangeland grasses to support this use on rangeland under Section 24(c) Special Local Need Registrations. In lieu of proposing a tolerance the site "rangeland" must be removed from the labeling. The registrant(s) must inform the Agency within 90 days which option is selected.

Rationale: No tolerances exist for residues of fenthion on rangeland. However, three 24(c) Special Local Need Registrations (WY780005, WY780007 and WY790005) pertain to use on rangeland as well as pasture grasses.

10. Pre-Slaughter intervals (PSIs)

Agency policy indicates that the maximum allowable pre-slaughter interval (PSI) cannot exceed 3 days. Data are being requested to determine an adequate tolerance level for 3 day PSI from rangeland and pasture grasses treatment and direct animal treatments. For use on rangeland, as well as pasture grasses, the labels must be revised to include a statement that livestock must be removed from the field during spraying and not allowed to graze until 7 days after treatment. Once the appropriate data are developed and tolerance levels are established for a 3 day PSI, this label restriction may be removed.

For direct animal treatments, present labeling requires a PSI from 14-45 days. This PSI must also be brought in line with the 3 day PSI policy of the Agency. However, the available data precludes any decision on the appropriateness of the established tolerances to support a change in the PSI to less than 14 days.

Rationale: A 28 day PSI currently exists for three Special Local Need registrations (WY780005, WY780007 and WY790005) if livestock feed on treated material within seven days of treatment or if they remain in the field while it is being sprayed. Also several products currently registered for direct animal treatment require PSIs of 14 to 45 days. This exceeds the maximum allowable pre-slaughter interval of 3 days and is considered impractical. The Agency is accepting only short PSIs (0 to 3 days) to reduce the chance of illegal residues in meat products.

11. Modified Use Label Statement in Lieu of Residue Data for Water, Irrigated Crops, Fish and Shellfish

The Agency will accept the following modified use labeling in lieu of residue data for water, irrigated crops, fish and shellfish: "Broadcast application may not be used over aquatic sites which include drainage ditches, stagnant and standing water and intermittently flooded areas adjacent to bodies of water used for commercial fishing, shellfish harvesting or irrigation purposes.

Rationale: Since the current use sites include tidal areas and bodies of water that could be used as irrigation water, residue data in water and shellfish are required. However, the suggested use modification labeling would prohibit the use of fenthion around bodies of water used for crop irrigation and potable water and where fish and shellfish are grown and/or harvested thus making it unlikely that fenthion residues would be present in potable water, irrigated crops, fish and shellfish. Registrants must inform the Agency within 90 days whether they intend to provide residue data, or use the label prohibition.

12. Endangered Species Concerns

The U.S. Fish and Wildlife Service (FWS) has determined that certain uses of fenthion may jeopardize the continued existence of endangered species or critical habitat of certain endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use to control mosquitoes does not result in jeopardy, and will issue notice of any necessary labeling. Labeling for the livestock and bird control uses will be required when FWS responds to EPA's request for further information.

No additional labeling is being required at this time. As explained below for the mosquito control use, labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn temporarily.

Rationale: In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to FWS findings that certain pesticides, including fenthion used to control mosquitoes, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988 the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling under the cluster program to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued. However, case by case endangered species consultation may still result in the need for labeling and this labeling can be required on uses not covered by the cluster program at any time.

13. Nontarget Organism Labeling

In order to comply in part to the statutory standard for continued registration, the Agency has determined that fenthion products must bear revised and updated labeling for hazards to nontarget organisms. The specific statements are given in Section IV. B. of this Standard.

Rationale: Available data show that fenthion is very highly toxic to birds, aquatic organisms, and honey bees. Precautionary label statements relative to the potential risks posed by fenthion to nontarget organisms will provide useful information to promote practices to limit such exposure of nontarget species to this pesticide.

14. Spray Drift Data Requirements

Droplet Spectrum and Spray Drift Field Evaluation tests are required. The droplet spectrum study must be performed to reflect the commonly-used nozzle and other equipment types which are used in the application of fenthion in various outdoor uses. The spray drift field evaluation must be performed to reflect the commonly-used application equipment, use patterns, and typical locations of use (including different weather factors) in the application of fenthion.

Rationale: The Agency is concerned about risks to off-site humans and wildlife caused by drift from mist-blower and cold fogger applications of fenthion. These tests are required because of the toxic nature of fenthion and because the methods used to apply fenthion (mist-blower and cold fogger) may lead to exposure of bystanders and wildlife. These tests will indicate the extent of possible drift of this chemical from normal applications and the data from these tests will enable the Agency to evaluate the potential risks from the drift.

15. Data Identified for Immediate Review

The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Section 158.240 - Residue Chemistry

171-4 - Nature of Residues (Metabolism [Plants and Livestock]). Tiered Study.
171-4 - Residue Storage Stability. Tiered Study.
171-4 - Magnitude of the Residue (Reassessment of residue data from direct application to animals based on nature of residues in livestock tissues)

Section 158.340 - Toxicology

81-7 - Tiered Study.
83-1 and 83-2 - Studies needed for calculation of an ADI for fenthion.
Special Testing - Ocular Effects. Needed to evaluate potential ocular effects of fenthion.

Section 158.440 - Spray Drift

201-1 and 202-1 - Needed to calculate human exposure to fenthion.

16. Continuation of Current Registrations

While the required data are being developed, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing fenthion may be sold, distributed, formulated and used subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration because data are missing or are inadequate [see FIFRA section 3(c)(2)(B) and 3(c)(7)]. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Required Labeling

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3, and below. Appendix II contains further information on label requirements.

1. Timeframes for Compliance

Pesticide products containing fenthion as an active ingredient may not be released for shipment by the registrant after June 30, 1989 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Standard.

Pesticide products containing fenthion as an active ingredient may not be distributed or sold after June 30, 1990 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Standard.

In addition to the above labeling requirements, the following information must appear on the labeling of all manufacturing-use and end-use products.

2. Manufacturing-Use Product Labeling

a. Ingredient Statement

The ingredient statement must list the active ingredient as:

ACTIVE INGREDIENT:
Fenthion (O,O-dimethyl-O-[4-(methylthio)-m-tolyl] phosphorothioate) . . . . . ___%

INERT INGREDIENTS. . . . . ___%

b. Use Pattern Statements

All products must state that they are intended for formulation into other manufacturing-use or end-use products for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below.

TERRESTRIAL FOOD CROP
(Agricultural Crops)

- o Agricultural Crops (nonbearing)

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

- o Alfalfa
- o Pasture (grasses)

TERRESTRIAL NONFOOD CROP
(Ornamental Plants and Forest Trees)

- o Forest Trees
- o Ornamental Herbaceous Plants (including begonia, chrysanthemum, geranium, lily, marigold, peony, phlox, petunia, snapdragon, verbena, and zinnia)
- o Ornamental Plants (nonbearing)
- o Ornamental Shade Trees (including arborvitae, ash, aspen, birch, dogwood, juniper, maple, oak, sweetgum, and tuliptree)
- o Ornamental Weedy Shrubs (including eunonymus, roses, and viburnum)

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

- o Bird Roosting Areas
- o Bridges
- o Buildings, Outdoor
- o Industrial Sites (pipe yards)

- o Loading Docks
- o Uncultivated Non-Agricultural Areas

AQUATIC FOOD CROP
(Agricultural Crops)

- o Rice

AQUATIC NONFOOD
(Aquatic Sites)

- o Aquatic Sites (including catch basins, ditches, lakes, marshes, ponds, stagnant streams, standing water, swamps, and tidal areas)

INDOOR
(Animals and Their Man-made Premises)

- o Beef Cattle
- o Dairy Cattle (non-lactating)
- o Hogs

(Agricultural Premises and Equipment)

- o Agricultural Premises
- o Beef Cattle Barns
- o Dairy Barns
- o Poultry Houses

(Domestic Dwellings)

- o Domestic Dwellings, Indoor
- o Domestic Dwellings, Outdoor

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

- o Wide Area and General Outdoor Treatments

(Commercial and Industrial Uses)

- o Commercial Establishments (Indoor, Inedible)
- o Commercial Establishments, Outdoor
- o Eating Establishments (Indoor, Inedible)
- o Food Processing Plants (Indoor, Inedible)

c. Environmental Hazards Statement

The following environmental hazard statement must appear on all manufacturing use labels:

> "This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

2. End-Use Product Labeling

All end-use products must bear the following labeling statements:

a. Ingredients Statement

Solvents or diluents currently declared as active ingredients in the ingredients statement must be included in the total of inert ingredients. The Agency does not have data indicating that these solvents are insecticidal.

b. Restricted Use Statement

All end-use products containing fenthion as an active ingredient with directions for use on agricultural crops, ornamental plants and forest trees, uncultivated agricultural outdoor areas, aquatic sites, livestock and bird roosting areas must bear the following restricted use labeling statements:

"RESTRICTED USE PESTICIDE

Due to Very High Acute Toxicity to Birds, Fish and Aquatic Invertebrates

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Certified applicators must also ensure that all persons involved in these activities are informed of the precautionary statements."

c. Environmental Hazards

One of the following environmental hazard statements must appear on the label of fenthion products:

Granular (Aquatic Larvicide)

"This pesticide is toxic to shrimp,fish and wildlife. Birds, fish, shrimp,and crabs in treated areas may be killed. Do not contaminate untreated water when disposing of equipment washwaters."

Nongranular (Nonaquatic Use Sites)

"This pesticide is highly toxic to shrimp, fish and wildlife. Birds, fish, shrimp, and crabs in treated areas may be killed. Do not apply directly to water or wetlands (including swamps, marshes, bogs, and potholes). Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters."

Nongranular (Aquatic Use Sites)

"This pesticide is highly toxic to shrimp, fish and wildlife. Birds, fish, shrimp, and crabs in treated areas may be killed. Do not apply where these are important resources. Drift and aquatic transport from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate untreated water when disposing of equipment washwaters."

d. Personal Protective Equipment and Work Safety

The following personal protective equipment and work safety statements must appear on the labeling of all products bearing the signal word "WARNING":

"USE ONLY WHEN WEARING THE FOLLOWING PERSONAL PROTECTIVE EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE: protective suit of one or two pieces that covers all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical-resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots); and a NIOSH or MSHA approved respiratory protection device. In addition, mixers/loaders must wear a chemical resistant apron. During equipment repair and cleaning, the respirator need not be worn.

IF MIXING/LOADING IS PERFORMED USING A CLOSED SYSTEM, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeve shirt; long-legged pants; chemical-resistant gloves; chemical-resistant apron; shoes and socks. Goggles or face shield must be worn when the system is under pressure. All other protective clothing and equipment required for use with open systems must be available nearby.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeve shirt and long-legged pants; shoes and socks. Chemical-resistant gloves must be available in the cab or cockpit and must be worn during entry to and exit from the application vehicle. All other protective clothing and equipment required for use during application must be available in the cab and must be worn when exiting the cab into treated area. When used for this purpose, contaminated clothing may not be brought back into the cab unless in an enclosure such as a plastic bag. REMEMBER - THIS CLOTHING IS INADEQUATE TO PROTECT YOU DURING REPAIR AND CLEANING OF APPLICATION EQUIPMENT AND EARLY REENTRY TO TREATED AREAS! REFER TO PROTECTIVE CLOTHING AND EQUIPMENT REQUIREMENTS ABOVE.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water and contact a physician immediately. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or using the toilet.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Clothing and that becomes heavily contaminated or drenched with fenthion must be destroyed according to State and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

The following personal protective equipment and work safety statements must appear on the labeling of all products bearing the signal word "CAUTION":

> USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, AND DISPOSAL OF THE PESTICIDE: Wear a long-sleeved shirt and long-legged pants, shoes, socks and chemical-resistant gloves,
>
> IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking eating, drinking, or using the toilet.
>
> AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Clothing worn during work must be laundered separately from household articles. Clothing that becomes heavily contaminated or drenched with fenthion must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

e. Bee Precautions

The following bee precautionary statement must appear on the label of all fenthion products intended for outdoor use (except granular formulations):

> "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are visiting the treatment area."

f. Reentry

The following reentry statements must appear on the labeling of all fenthion products labeled for use on ornamentals:

Reentry

"Reentry into treated area is prohibited for 24 hours (1 day) after the end of application, unless the protective clothing specified on this label for early reentry is worn.

FOR EARLY REENTRY INTO TREATED AREAS BEFORE SPRAYS HAVE DRIED [OR DUST HAS SETTLED, as applicable] wear all protective clothing specified on this label for an applicator.

FOR EARLY REENTRY INTO TREATED AREAS AFTER SPRAYS HAVE DRIED [OR DUST HAS SETTLED, as applicable] wear protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical-resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots).

g. Storage and Disposal

All products must have the appropriate storage and disposal statements on the label. Refer to Appendix II for the appropriate statements.

h. Use Directions from EPA's Index to Pesticide Chemicals

For avicide uses: Applications are to be made by persons trained in bird control. Local, state and federal permits must be obtained before use. Do not use fenthion as a surface treatment. Use only in liquid-filled perches. Do not allow fenthion to contact skin. Not for use inside food storage, processing or handling premises; substance must not contaminate foods or feeds. Do not expose this substance in any manner that may endanger nontarget birds and other animals. Keep areas to be treated free of bird food and feed. Do not apply, or allow to drift, to roosting areas near human habitation or non-target animals. Install 'perches' out of reach of irresponsible persons. Collect and properly dispose of all dead birds and drain substance from perches when desired control is achieved.

For domestic dwelling, indoor residual application: Apply as a coarse spray or by paint brush. Treat around doors, windows, and light fixtures. Repeat as needed. Do not use in areas where children or pets can come into direct contact with treated surfaces.

For domestic dwelling, indoor crack and crevice treatment: Apply as a crack and crevice treatment. Do not use in areas where children or pets can come into direct contact with treated surfaces.

For domestic dwelling, outdoor residual application: Apply as a coarse spray or by paint brush. For ants, thoroughly wet hills and runways. For house fly, spray around windows and other surfaces frequented by pests.

For commercial and industrial uses ((commercial establishments, indoor, inedible) (eating establishments, indoor, inedible) and (food processing plants, indoor, inedible)), indoor application: Apply as a coarse spray, or with a paint brush, or as a crack and crevice treatment.

For commercial establishments, outdoor residual application: Apply as a coarse spray or by paint brush. For ants, thoroughly wet hills and runways. For house fly, spray around windows and other surfaces frequented by pests.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing-use product.

2. The data requirements listed in Tables A and B[5]

3. The labeling requirements specified for manufacturing-use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[5] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard.

Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing-use product.

2. The labeling requirements specified for manufacturing-use products in Section IV.

3. The data requirements listed in Table A.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

C. End-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If eligible for the formulator's exemption[5], the data requirements listed in Table C (if included).

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[6] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B)

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

5. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

D. End-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If not eligible for the formulator's exemption, the data requirements listed in Table A and Table C (if included).

3. If eligible for the formulator's exemption, the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

5. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[7]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR sec. 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[7] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements.

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data

that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant *and* proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the

Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5385 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data then is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing-use product, these data are listed in Table B. If you have an end-use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end-use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELS

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing-Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[8]

   b. Confidential Statement of Formula (EPA Form 8570-4)

   c. Generic Data Exemption Statement (Formulator's Exemption Statement) (EPA Form 8570-27), if applicable.

   d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80 - 152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

   a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

   b. Two copies of any required product-specific data (see Table B).

   c. Product Specific Data Report (EPA Form 8580-4).

   d. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

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[8] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing-Use products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments^x (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Generic Data Exemption Statement (Formulator's Exemption Statement) (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manger:

a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

b. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End-Use Products containing the subject pesticide as, sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. Generic Data Exemption Statement (Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4 if Table C lists required product-specific data.

c. Three copies of draft labeling, as specified in Chapter IV.D. Required labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

D. End-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Three copies of draft labeling, as specified in Chapter IV.D. Required labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

Applications for full federal registration of intrastate products are required to be submitted no later than July 31, 1988.

F. Addresses

The required information must be submitted to the following address:

George T. LaRocca (PM 15)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when the data are to be submitted, based on the date of receipt of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1/]
Part 158, Subpart C, Product Chemistry						
Product Identity and Composition						
61-2 - Description of Starting Materials and Manufacturing Process	TGAI	All	Yes	40085801 40223002	Reserved[2/],[3/],[4/]	03/21/87
61-3 - Discussion of Formation of Impurities	TGAI	All	Yes	40085801 40223002	Reserved[2/],[3/],[5/]	03/21/87
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	Yes	40223001	Reserved[2/],[3/],[6/]	09/22/87
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	Yes	40085802	Reserved[2/],[3/],[7/]	09/22/87
63-3 - Physical State	TGAI	All	Yes	40085802	Reserved[2/],[3/],[7/]	09/22/87
63-4 - Odor	TGAI	All	Yes	40085802	Reserved[2/],[3/],[7/]	09/22/87
63-5 - Melting Point	TGAI	All	Yes	40085802	Reserved[2/],[3/],[8/]	09/22/87
63-6 - Boiling Point	TGAI	All	Yes	40085802	Reserved[2/],[3/],[9/]	09/22/87

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Part 158, Subpart C, Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	yes	40085802	Reserved[2]/,[3]/	09/22/87
63-8 - Solubility	TGAI or PAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
63-9 - Vapor Pressure	TGAI or PAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
63-10 - Dissociation Constant	TGAI or PAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
63-11 - Octanol/Water Partition Coefficient	PAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
63-12 - pH	TGAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
63-13 - Stability	TGAI	All	Yes	40085802	Reserved[2]/,[3]/	09/22/87
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No	09/22/87

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Part 158, Subpart C, Product Chemistry - Footnotes

1/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Comprehensive Data Call-In letter dated April 29, 1986.

2/ Required for all technical grade fenthion products. The 95% (EPA Reg. No. 11556-36), 93% EC (EPA Reg. No. 3125-148) and 93% (EPA Reg. No. 3125-197) products are considered technical products.

3/ Data submitted in response to the April 29, 1986 Comprehensive Data Call-In were not received in time to be included in the data base reviewed for this standard. Therefore no determination has been made as to the adequacy of this data in satisfying the data requirement. Should the data be found unacceptable after Agency review a new study is required under Section 3(c)(2)(B).

4/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of starting materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each starting material must be provided, along with information regarding the properties of each starting material used to manufacture each product.

5/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the starting materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at ≥ 0.1% (w/w), and each toxicologically significant inert. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Part 158, Subpart C, Product Chemistry - Footnotes (continued)

7/ All physicochemical characteristics of the technical product, or the pure active ingredient, as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

8/ Required if the technical chemical is a solid at room temperature.

9/Required if the technical chemical is a liquid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.240 Residue Chemistry					
171-2 - Chemical Identity	TGAI	No		Yes[2]/	
171-3 - Directions for Use		Yes	Product Label	No	
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Partially	00066832, 00075108	Yes[3]/,[4]/	18 Months
- Livestock	PAIRA	Partially	00115886 00154967	Yes[5]/	18 Months
171-4 - Residue Analytical Methods - Plant and Animal Residues	TGAI and metabolites	Partially	00093415, 00115887, 00115889, 00115895, 00116381, 00116748, 00116750, 00116751, 00154967	Yes[6]/,[7]/	15 Months
171-4 - Storage Stability Data	EP and metabolites	Partially	00115889, 00154967	Yes[7]/,[8]/,[9]/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.240 Residue Chemistry (cont'd)						
171-4 - Magnitude of the Residues in Plants						
- Crop Field Trials						
- Cereal Grains Group[10]						
o Rice	TEP		Yes	00116749 00154967	No	
- Forage, Fodder, and Straw of Cereal Grains Group[11]/,[12]/						
o Rice Straw	TEP		Partially	00154967	Yes[13]/	30 Months
- Grass Forage, Fodder, and Hay Group	TEP		Partially	00032871, 00065775, 00065776, 00116399	Yes[14]/,[15]/,[16]/,[17]/	30 Months
- Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group[18]/,[19]/						
o Alfalfa	EP		Partially	00032871, 00065775, 00065776	Yes[20]/,[21],[22]/	30 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.240 Residue Chemistry (cont'd)						
171-4 - Magnitude of the Residues						
- Crop Field Trials (cont'd)						
- Meat/Milk/Poultry/Eggs	TEP		Partially	00062094, 00071969, 00093415 00093416 00093422 00093459, 00115216 00115886, 00115889, 00115898, 00115908, 00115928, 00115932, 00116381, 00116386, 00116398, 00116748	Reserved[23]/	
- Potable Water			No		Yes[24]/	15 Months
- Fish and Shellfish			No		Yes[25]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.240 Residue Chemistry - Footnotes

1/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

2/ The same chemical identity data required as under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables (A and B).

3/ The uptake, distribution, and metabolism of ring-labeled $[^{14}C]$ fenthion in alfalfa and a representative grass following foliar or broadcast application at a rate sufficiently high to permit ^{14}C-residue characterization. Residue identities must be confiremed by a method such as GC, HPLC, and/or mass spectrometry. Data reflecting solvent extraction of fenthion must also be provided. Representative samples from the required metabolism studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

4/ The registrant should complete and submit all plant metabolism data to the Agency for review prior to initiation of residue field trials and processing studies.

5/ Metabolism studies must be submitted utilizing ruminants and poultry. Animals must be dosed for at least 3 days with ring-labeled $[^{14}C]$ fenthion at a concentration in the total diet that will result in sufficient residues in tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dosing. Milk and eggs must be collected twice daily. ^{14}C-residues in muscle, fat, kidney, liver, milk, and eggs must be characterized. In addition, cattle and swine must be dermally dosed with ring-labeled $[^{14}C]$ fenthion at a concentration that will result in sufficient residues in the tissues for characterizations. Animals must be sacrificed 24 hours after treatment and residues characterized in muscle, fat, kidney, liver, and skin (swine only). Representative samples from the studies requested above must also be analyzed using accepted enforcement methods to ascertain their validity.

6/ Residues of FSO [0,0-dimethyl-0-[4-(methylsulfinyl)-m-toly]phosphorothioate] and FSO_2 [0,0-dimethyl-0-[4-(methylsulfonyl)m-toly]phosphorothioate] in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB 203734/AS.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.240 Residue Chemistry - Footnotes (cont'd)

7/ Additional methods, validation data, residue data (for representative commodities), and stability of residues in storage may be required if the metabolism studies requested in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" reveal additional metabolites of toxicological concern in plants or animals.

8/ The storage intervals and conditions of samples used to support all established tolerances for residues of fenthion and its cholinesterase-inhibiting metabolites must be submitted. These data must be accompanied by data depicting the percent decline in residues of fenthion and its cholinesterase-inhibiting metabolites at the times and under the conditions specified. Additional stability studies are not required for: (i) fenthion and $FOSO_2$ in cow "steak" and fat stored at 24°C for up to 6 hours; (ii) fenthion in cow liver stored at 24°C for up to 6 hours; and (iii) fenthion and FOSO in or on alfalfa stored at 0 to -10°F for up to 62 weeks. On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

9/ All requested residue data must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues of fenthion and its cholinesterase-inhibiting metabolites under the conditions and for the time intervals specified, with the exception of: (i) fenthion and $FOASO_2$ in cow "steak" and fat stored for up to 6 hours at 24°C; (ii) fenthion in cow liver stored at 24°C for up to 6 hours; and (iii) fenthion and FOASO in or on alfalfa stored at 0 to -10°F for up to 62 days.

10/ If the registrant wishes to propose a crop group tolerance, then use directions must be proposed and appropriate supporting residue data submitted for corn (fresh, sweet, and dried field), sorghum, and wheat.

11/ If the registrant wishes to propose a crop group tolerance, then additional data must be submitted to support the established tolerance for residues of fenthion in or on the representative group member rice straw.

12/ If the registrant wishes to propose a crop group tolerance, then use directions must be proposed and appropriate supporting residue data submitted for additional representative group members (wheat, sorghum and corn).

13/ Data must be submitted depicting fenthion residues of concern in or on rice straw harvested 30 days following the last of three applications of an EC formulation at 0.1 lb ai/A. Tests must be conducted in California.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.240 Residue Chemistry - Footnotes (cont'd)

[14]/ Data must be submitted reflecting residues of fenthion and its cholinesterase-inhibiting metabolites in or on Bermuda grass, bluegrass, and bromegrass or fescue (as fresh grass and hay) treated with four broadcast applications (at 21-day intervals) of a G Formulation at 0.2 lb ai/A and, in separate tests, four broadcast applications (at 21-day intervals) of an EC formulation at 0.1 lb ai/A as: (i) a mist spray by ground equipment using both low- and high-volume application; (ii) a ULV nonthermal aerosol application; and (iii) an aerial application in a conventional dilution applied at a rate of 1 gal finished spray/A. Water must be used as a carrier and tests must reflect a 0-day posttreatment interval. Tests must be conducted in Arkansas (3%), Kansas (4%), Kentucky (6%), Missouri (11%), New York (5%), Oklahoma (4%), Pennsylvania (4%), Tennessee (4%), Texas (13%), and Virginia (3%) which produced ca. 57% of the total 1982 domestic hay crop (other than alfalfa and small grains) and which may represent pasture grasses as well (production figures in parentheses obtained from the 1982 Census of Agriculture, Vol. 1, Pt. 51, p. 330). Tests reflecting the ULV nonthermal aerosol applications must be conducted in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Tennessee, and Texas to support the Federal registration, and in Idaho, Missouri, Oregon, Vermont, and Washington to support the uses permitted under SLN Nos. ID-800056, MO-840002, OR-800085, UT-800010, and WA-780051.

[15]/ Data must be submitted depicting residues of fenthion and its cholinesterase-inhibiting metabolites in or on Bermuda grass, bluegrass, and bromegrass or fescue (as fresh grass and hay) harvested 0-days following two aerial applications at 21-day intervals using an oil carrier of the 9.76 lb ai/gal EC formulation at 0.075 lb ai/A. Tests must be conducted in Wyoming.

[16]/ Data must be submitted depicting residues of fenthion and its cholinesterase-inhibiting metabolites in or on Bermuda grass, bluegrass, and bromegrass or fescue (as fresh grass and hay) harvested on the day of the last of four broadcast foliar applications (at 21-day intervals) of the 7 lb ai/gal EC formulation (by aircraft using ULV equipment and a water carrier) at 0.1 lb ai/A. Tests must be conducted in Oregon where this use is permitted.

[17]/ Data must be submitted depicting residues of fenthion and its cholinesterase-inhibiting metabolites in or on Bermuda grass, bluegrass, and bromegrass or fescue (as fresh grass and hay) harvested on the day of the last of four applications (made at 21-day intervals) of the 4 lb ai/gal EC formulation at 0.1875 lb ai/A. Tests must be conducted in California where this use is permitted.

[18]/ If the registrant wishes to propose a crop group tolerance, then use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member clover (*Trifolium* sppl).

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.240 Residue Chemistry - Footnotes (cont'd)

19/ If the registrant wishes to propose a crop group tolerance, then additional data are required to support the existing tolerance for residues of fenthion and its cholinesterase-inhibiting metabolites in or on alfalfa.

20/ Data must be submitted reflecting residues of fenthion and its cholinesterase-inhibiting metabolites in or on fresh alfalfa and alfalfa hay harvested 0-days following the last of foliar broadcast applications (one application/cutting) at 21-day intervals of a G formulation at 0.2 lb ai/A, and, in a separate test, an EC formulation at 0.1 lb ai/A. Separate tests with the EC formulation are to be made as: (i) a mist spray by ground equipment using both high- and low-volume applications; (ii) an aerial application conventionally diluted and applied at a rate of 1 gal finished spray/A; and (iii) a ULV nonthermal aerosol application. Water must be used as a carrier. Tests reflecting a ULV nonthermal aerosol application must be conducted in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Tennessee, and Texas to support the Federal registration, and in Idaho, Missouri, Oregon, Vermont, and Washington to support the uses permitted under SLN Nos. ID-800056, MO-840002, OR-800085, UT-8000010, and WA-780051. All remaining tests must be performed in California (7%), Iowa (7%), Mississippi (5%), Minnesota (7%), Nebraska (6%), South Dakota (6%), and Wisconsin (13%), which, together with the neighboring States of Illinois (3%), Montana (3%), North Dakota (3%), and Ohio (2%), collectively produced 62% of the total alfalfa crop in 1984 (production figures in parentheses were obtained from Agricultural Statistics, 1985, p. 242).

21/ Data must be submitted depicting residues of fenthion and its cholinesterase-inhibiting metabolites in or on fresh alfalfa and alfalfa hay harvested 0-days following the last of broadcast foliar applications at 21-day intervals (one treatment per cutting) of the 7 lb ai/gal EC formulation (applied by aircraft using ULV equipment and water as a carrier at 0.1 lb ai/A. Tests must be conducted in Oregon which is the only state where this use is permitted.

22/ Data depicting residues of fenthion and its cholinesterase-inhibiting metabolites in or on fresh alfalfa and alfalfa hay harvested 0-days following the last of broadcast foliar applications (one application/cutting) at 21-day intervals (by conventional ground and aircraft equipment) of the 4 lb ai/gal EC formulation at 0.1875 lb ai/A. Tests must be conducted in California which is the only state where this use is permitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.240 Residue Chemistry - Footnotes (cont'd)

23/ Currently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in fat, meat, and meat byproducts of cattle, hogs, poultry and milk will be determined.

24/ Data must be submitted depicting the nature and magnitude of the residue in raw water following treatment of various bodies of water (i.e., lakes, ponds, marshes, etc.) with multiple applications (at 21-day intervals) of each of the following: (i) an RTU formulation at 1.5 ga. finished spray/A; (ii) a D and G formulation (in separate tests) at 0.2 lb ai/A; and (iii) an EC formulation at 0.05 lb ai/A. Degradation products in water should be identified and quantified. Should detectable residues of concern occur in water, then tolerance proposals for irrigated crops as well as an estimated appropriate level in water will be required. In lieu of submitting data the following label restriction may be implemented: Broadcast use over aquatic areas which include drainage ditches, stagnant and standing water and intermittantly flooded areas around other bodies of water. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

25/ If detectable residues of concern are found in water then residue and metabolism studies in fish will be required. Since the present use sites include tidal areas, a residue study with shellfish (a mollusk and a crustacean) will also be required. In lieu of submitting data the following label restriction may be implemented: Broadcast use over aquatic areas which include drainage ditches, stagnant and standing water and intermittantly flooded areas around other bodies of water. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	PAIRA	A B C D G H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	PAIRA	A B C D G H	Yes	40110401[2]/	Reserved[3]/	06/19/87
161-3 - On Soil	PAIRA OR TGAI	A B G	No		Yes	9 Months
161-4 - In Air	PAIRA OR TGAI	A B	No		Yes	9 Months
Metabolism studies - Lab						
162-1 - Aerobic Soil	PAIRA	A B G H	Yes	00114318	No	-----
162-2 - Anaerobic Soil	PAIRA OR TGAI	A B C	Yes	00114318	No	-----
162-3 - Anaerobic Aquatic	PAIRA OR TGAI	C D G	No		Yes	12/20/88
162-4 - Aerobic Aquatic	PAIRA OR TGAI	C D	No		Yes	12/20/88

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.290 Environmental Fate (continued)						
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	PAIRA	A B C D G H	Partially	00115918 40194201[4]/	Reserved[3]/,[4]/	09/22/87
163-2 - Volatility (Lab)	TEP	A B	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A B	No		Reserved[5]/	------
Dissipation Studies - Field						
164-1 - Soil	TEP	A B H	No		Yes[6]/	12/20/88
164-2 - Aquatic (Sediment)	TEP	C D	No		Yes[6]/	12/20/88
164-3 - Forestry	TEP	G	No		Yes[6]/	27 Months
164-4 - Combination and Tank Mixes	TEP	N/A	No		No[7]/	---
164-5 - Soil, Long-Term	TEP	A B H	No		Reserved[8]/	---

TABLE
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.290 Environmental Fate (continued)						
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A B C	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A B C	No		Reserved[9]/	---
165-3 - Irrigated Crops	TEP	C D	No		Yes	39 Months
165-4 - In Fish	PAIRA OR TGAI	A B C D G	No		Yes[10]/	12 Months
165-5 - In Aquatic Nontarget Organism	TEP	D G	No		Reserved[11]/	---
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	B	No		Yes[12]/	27 Months
132-2 - Soil Dissipation	TEP	N/A	No		No	---
132-3 - Dermal Exposure	TEP	B	No		Optional[13]/	---
132-4 - Inhalation Exposure	TEP	B	No		Optional[13]/	---
Sec. 158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A B C D G H	No		Yes[14]/	12 Months
202-1 - Drift Field Evaluation	TEP	A B C D G H	No		Yes[14]/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.290 Environmental Fate - Footnotes
Sec. 158.390 Reentry Protection - Footnotes
Sec. 158.440 Spray Drift - Footnotes

1/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Data Call-In Letter dated April 29, 1986.

2/ Data have been received but have not completed the Agency's review process. Therefore, no determination can be made at this time as to the adequacy of the data in meeting this data requirement.

3/ If, at the conclusion of Agency's data review process, the data is found unacceptable a new study will be required under Section 3(c)(2)(B) of FIFRA.

4/ Studies on three other soils are required. At least one of these studies should be an aged column leaching study (preferably on sandy loam soil) with adequate identification of soil and leachate residues. The other studies should be unaged adsorption/desorption with K_d values determined.

5/ Field volatility requirement is reserved pending receipt and evaluation of acceptable laboratory volatility data. If required, the field volatility study will be due within 15 months after notification of requirement by the Agency.

6/ Method sensitivity should be about 10 ppb for soil. The degradates identified in the metabolism studies should be monitored, including 3-methyl-4-(methylsulfonyl)-phenol and 3-methyl-4-(methylsulfinyl)-phenol.

7/ Combination and tank mixes are not being addressed in this Standard.

8/ Long-term field dissipation data requirement is deferred pending receipt of acceptable field dissipation data (164-1). If required, the long-term field dissipation study will be due within 50 months after notification of the requirement by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.290 Environmental Fate - Footnotes (continued)
Sec. 158.390 Reentry Protection - Footnotes
Sec. 158.440 Spray Drift - Footnotes

9/ Field crop rotation data requirement is deferred pending receipt of acceptable confined rotational crop accumulation data. If required, the field crop rotation study will be due within 50 months after notification of the requirement by the Agency.

10/ The registrant should first submit an octanol/water partition coefficient.

11/ Aquatic non-target organism data requirement is reserved pending the results of the laboratory studies of pesticide accumulation in fish (165-4). If required, the aquatic non-target organism pesticide accumulation study will be due within 12 months after notification of the requirement by the Agency.

12/ For ornamental use patterns, the registrant is required to propose an acceptable reentry interval based either upon data: (i) on dissipation of residues (decline curve), on human exposure to those residues, and on toxicity of the residues or (ii) on determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker environment.

13/ Human exposure monitoring data may be submitted at the registrant's option. If dermal exposure data are submited, inhalation exposure data must also be submitted.

14/ The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the drop spectra that are associated with actual field-use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A B C D G I	Yes	00132312 40186704[2]/	Reserved[3]/	06/19/87
81-2 - Acute Dermal - Rat	TGAI	A B C D G I	Yes	00132314 40186705[2]/	Reserved[3]/	06/19/87
81-3 - Acute Inhalation - Rat	TGAI	A B C D G I	Yes	00132317 40186707[2]/	Reserved[3]/	06/19/87
81-4 - Eye Irritation - Rabbit	TGAI	A B C D G I	Yes	00132319 40186708[4]2	Reserved[3]/	06/19/87
81-5 - Dermal Irritation - Rabbit	TGAI	A B C D G I	Yes	00132319 40186709[2]/	Reserved[3]/	06/19/87
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A B C D G I	Yes	40186710[2]/	Reserved[3]/	06/19/87
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A B C D G I	Yes	40229201[2]/	Reserved[3]/	09/22/87
Subchronic Testing						
82-1 - 90-Day Feeding -						
- Rodent	TGAI	A B C D G I	No		Yes[4]/	03/20/88
- Nonrodent	TGAI	A B C D G I	No		Yes[4]/	12/20/87

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.340 Toxicology (cont'd)						
Subchronic Testing (cont'd)						
82-2 - 21-Day Dermal	TGAI	A B C D G I	Yes	40329501[2]/	Reserved[3]/	09/22/87
82-3 - 90-Day Dermal	TGAI	A B C D G I	No		No	------
82-4 - 90-Day Inhalation	TGAI	A B C D G I	No		Yes[5]/	15 Months
82-5 - 90-Day Neurotoxicity	TGAI	A B C D G I	No		Reserved[6]/	------
Chronic Testing						
83-1 - Chronic Toxicity -						
- Rodent	TGAI	A B C D G I	No		Yes[7]/	11/20/90
- Nonrodent	TGAI	A B C D G I	Partial	00081363, 00132341, 00132356, 00147245	Yes[7]/	11/20/90
83-2 - Oncogenicity -						
- Rat	TGAI	A B C D G I	No		Yes[7]/	11/20/90
- Mouse	TGAI	A B C D G I	No		Yes[7]/	11/20/90

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.340 Toxicology (cont'd)						
Chronic Testing (cont'd)						
83-3 - Teratogenicity -						
- Rat	TGAI	A B C D G I	Yes	00132346 40329401[2]/	Reserved[3]/	12/21/87
- Rabbit	TGAI	A B C D G I	Yes	00132347 40462701[4]/	No	------
83-4 - Reproduction -						
-Rat or Mouse	TGAI	A B C D G I	Partial	00081115, 00132344	Yes[8]/	12/28/89
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A B C D G I	Yes	00132349	No	------
84-2 - Chromosome Aberration	TGAI	A B C D G I	Yes	00132348 00132349 00132350 00132351 00132352 00132353	No	------
84-2 - Other Mechanism of Mutagenicity	TGAI	A B C D G I	Yes	00147316	No	------

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.340 Toxicology (cont'd)						
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A B C D G I	Yes	00115926[2]/ 00116396[2]/ 00132309[2]/ 00154967[2]/	Reserved[3]/	04/26/88
85-2 - Dermal Penetration	PAI or PAIRA	A B C D G I	No		No	------
Special Testing Ocular Effects						
- Acute Oral - Rat	TGAI	A B C D G I	No		Yes[9]/	9 Months
- Subchronic Oral - Rat	TGAI	A B C D G I	No		Yes[10]/	15 Months
- Six-Month Oral - Dog or Rabbit or Monkey	TGAI	A B C D G I	No		Yes[11]/	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.340 Toxicology - Footnotes

1/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Data Call-In Letter dated April 29, 1986.

2/ Data have been received but have not completed the Agency's review process. Therefore, no determination can be made at this time as to the adequacy of the data in meeting this data requirement.

3/ If, at the conclusion of Agency's data review process, the data is found unacceptable a new study will be required under Section 3(c)(2)(B) of FIFRA.

4/ Subchronic feeding studies are not required if chronic feeding studies are conducted.

5/ A subchronic inhalation test is required if use of fenthion results in repeat inhalation exposure at levels likely to be toxic.

6/ Requirement is contingent upon results of the acute delayed neurotoxicity study in hens. If required, the study will be due within 15 months after notification of requirement by the Agency.

7/ Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range-finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.

8/ Either the raw data from the existing study must be submitted to remedy its deficiencies or a new multi-generation reproduction study is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.340 Toxicology - Footnotes (cont'd)

9/ Acute Tests in Rats: (Recommended; acute sublethal doses; tests performed pretest, at 4 days and repeated at intervals until full recovery). Observations should include:
- cholinesterase activity (blood); and
- retinal electrical activity (electroretinography).

10/ Subchronic Study in Rats: (Recommended; 3 orally treated and 1 control group, 10 rats/sex/group. Observations pretest and at intervals for at least 90 days; doses based on results of acute study). Observations should include:
- cholinesterase activity (blood, brain at termination);
- retinal electrical activity (electroretinography);
- opthalmoscopic observations;
- fundis observations/photographs;
- clinical observations of potential cholinergic signs;
- body weights; and
- histopathology of the eye; light and EM, including intra- and extraocular muscle, optic nerve and retina.

11/ Nonrodent (Dog/Rabbit/Monkey) Study: (Recommended; 3 orally treated and 1 control group, 5 animals/sex/group. Observations pretest and at intervals for at least 6 months). Observations should include:
- cholinesterase activity (RBC, plasma; at termination brain, oculomotor muscle, retina);
- retinal electrical activity (electroretinography);
- corneal sensitivity;
- slit lamp biomicroscopic examinations;
- corneal thickness;
- corneal curvature;
- opthalmoscopic/fundis observations/photographs;
- intraocular pressure;
- refractivity of cornea and lens;
- clinical observations of potential cholinergic signs;
- body weights; and
- histopathology of the eye; light and EM, including intra- and extraocular muscle, optic nerve and retina.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.490 Wildlife and Aquatic Organisms						
Avian And Mammalian Testing						
71-1 - Avian Acute Oral Toxicity	TGAI	A B C D G H [I][3]/	Yes	00160000 05000975 40186701[4]/	No	06/19/87
	Degradate	A [B][5]/ C D G [I][6]/	No		Yes[7]/	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Waterfowl	TGAI	A B C D G H [I][8]/	Yes	00062189 40186703[4]/	No	06/19/87
	Degradate	A [B][5]/ C D G [I][6]/	No		Yes[7]/	9 Months
- Upland Game Bird	TGAI	A B C D G H [I][8]/	Yes	00062189 40186702[4]/	No	06/19/87
	Degradate	A [B][5]/ C D G [I][6]/	No		Yes[7]/	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A [B][9]/ C [D][10]/G	No		Yes[11]/	24 Months (12-Month Progress Report)
	Degradate	A [B][9]/ C [D][10]/G	No		Yes[12]/	24 Months (12-Month Progress Report)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
Avian And Mammalian Testing (cont'd)						
71-4 - Avian Reproduction						
- Waterfowl	TGAI	A [B][13]/ C D G [I][15]/	No		Yes[14]/	24 Months (12-Month Progress Report)
	Degradate	A [B][13]/[C][14]/D G [I][15]/	No		Reserved[16]/	------
- Upland Game Bird	TGAI	A [B][13]/ C D G [I][15]/	No		Yes[14]/	24 Months (12-Month Progress Report)
	Degradate	A [B][13]/[C][14]/G	No		Reserved[16]/	------
71-5 - Simulated and Actual Field Testing for Mammals and Birds	TEP	A [B][5]/C D G [I][6]/	Partial	00107081* 00116380* 40247101* 40247102* 40247104*	Yes[17]/,[18]/	48 Months (Protocols 6 Months) (Annual Progress Reports each 12 months)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing						
72-1 - Freshwater Fish Acute Toxicity						
- Warmwater	TGAI	A B C D G H [I][19]/	Yes	05000819 05014941 40274101[4]/	No	06/19/87
	TEP	C D	Partial	40094602[20]/	Yes[21]/	9 Months
	Degradate	A [B][9]/ C D G [I][6]/	No		Yes[22]/	9 Months
- Coldwater	TGAI	A B C D G H [I][19]/	Yes	40094602 40214201[4]/	No	06/19/87
	TEP	C D G	Partial	40094602[20]/	Yes[21]/	9 Months
	Degradate	A [B][9]/ C D G [I][6]/	No		Yes[22]	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A B C D G H I	Yes	40094602 40246401	No	------
	TEP	C D G	Partial	40094602[20]/	Yes[21]/	9 Months
	Degradate	A [B][9]/ C D G [I][6]/	No		Reserved[23]/	------

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing (cont'd)						
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	[A][9]/ [B][17]/D G	Partial	40247105[24]/ 40228401[25]/ 40564101[4]/ 40495501[4]/	Reserved[26]/	09/22/87
	TEP	D G	Partial	40094602[20]/	Yes[21]/	12 Months
	Degradate	[A][9]/ [B][9]/ D G	No		Reserved[23]/	------
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A [B][9]/ C D G	Yes	40564102[4]/	Reserved[27]/	01/22/88
	Degradate	A [B][9]/ C D G	No		Reserved[28]/	------
72-5 - Fish Life Cycle	TGAI	A [B][9]/ C D G	No		Reserved[28]/	------
72-6 - Aquatic Organism Accumulation	TGAI	A [B][9]/ C D G [I][6]/	No		es[29]/	12 Months
72-7 - Simulated or Actual Field Testing	TEP	A [B][9]/ C D G G [I][6]/	Partial	00107081* 00116380* 00154963* 40247103*	Yes[18]/,[30]/	09/22/90

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
70-1 - Special Testing						
- Residue Monitoring	TEP	I	No		Yes[31]/,[33]/	48 Months (Protocol 6 Months) (12-Month Progress Report)
- Bivalve Testing	TGAI	A B C D G	No		Yes[34]/	18 Months (Protocol 6 Months)
- Reptile and Amphibian Testing	TGAI	A B D G	No		Yes[35]/	18 Months (Protocol 6 Months)
Sec. 158.540 Plant Protection Testing						
122-1 - Seed Germination/ Seedling Emergence	TGAI	[B][32]/D G	Yes	40110402[4]/	Reserved[4]/	06/19/87
- Vegetative Vigor	TGAI	[B][32]/D G	Yes	40110402[4]/	Reserved[4]/	06/19/87
122-2 - Aquatic Plant Growth	TGAI	[B][32]/D C	Yes	40186711[4]/ 40186712[4]/ 40186713[4]/ 40186714[4]/ 40186715[4]/	Reserved[4]/	06/19/87

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes
Sec. 158.540 Plant Protection Testing - Footnotes

* Could fulfill requirement in conjunction with other test data.

[1]/Degradate = Major degradates of fenthion; 3-methyl-4-(methylsulfonyl)-phenol and 3-methyl-4-(methylsulfinyl)-phenol.

[2]/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Data Call-In Letter dated April 29, 1986.

[3]/The use of fenthion on livestock is categorized as an indoor use; however, exposure to birds is possible. Therefore, a study is required for products registered for direct application on cattle and swine. Also required for manufacturing use products which, as a technical, are solids and used to formulate all products registered for indoor use.

[4]/Data have been received but have not completed the Agency's review process. Therefore, no determination can be made at this time as to the adequacy of the data in meeting this data requirement.

[5]/Required only to support registrations of those formulations used to control mosquitoes and to control birds in industrial areas.

[6]/Required only to support registration of those formulations that are applied directly to cattle or swine.

[7]/Required because of series of bird kills reported by Hanson and Howell (1981) suggest that magpies were killed by feeding on backs of cattle; in some cases, several weeks after the livestock had been treated. Since available information indicates fenthion has a relatively short half-life, it is possible that some degradate is toxic to birds. One avian dietary study must be conducted with either an upland species or a waterfowl, major degradates of fenthion (see note No. 1).

[8]/Required to support registration of those formulations that are applied directly to cattle or swine. Also, one avian dietary test is required with either an upland species or a waterfowl to support all registered manufacturing-use products used to make any indoor formulation.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

[9]/ Required only to support registration of those formulations used for mosquito control.

[10]/Required only to support registration of nongranular formulations.

[11]/The use of fenthion is suspected of killing mammals (Deweese et al. 1981, MRID No. 40247101). Acute toxicity testing is required to determine the toxicity of fenthion to mammals.

[12]/The use of fenthion is suspected of killing mammals following application at rates that would not have been expected to cause residues lethal to mammals (Deweese et al. 1981, MRID No. 40247101). It is possible that a degradate is toxic to mammals. Acute toxicity testing is required to determine the toxicity of fenthion degradates (see footnote No. 1) to mammals.

[13]/Required to support registrations of all mosquito control formulations that involve multiple applications per season. Also required for formulations used to control birds because bird perches are maintained regularly for continuous control and, subsequently, extended exposure to nontarget birds.

[14]/Required because multiple applications are permitted.

[15]/Required to support registration of those formulations that are applied directly to cattle or swine because incidents reported by Hanson and Howell (1981) indicate toxic effects occur for several weeks after treatment, suggesting chronic exposure.

[16]/Reserved pending receipt of avian acute and dietary test results with degradates.

[17]/The available field tests do not fulfill the requirements for definitive field studies. They do not provide quantitative information on the effects of fenthion on birds and mammals.

[18]/Terrestrial Field Studies
The use of fenthion on the following sites has been determined to cause adverse effects to terrestrial organisms. The following chart indicates the types of terrestrial field studies required for each use site per category. The terms used to describe the types of studies are:

a. Preliminary field study, which is a multisite, multilocation screening study to detect acute effects to mammals and/or birds. Multisite means several (8) treatment and sampling areas within each location. Location refers

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

to geographically or ecologically distinct portions of the range where fenthion is applied for each particular use site (e.g., pastureland mosquito control or bird control around manmade structures). The results of these preliminary screening studies will be used to determine the need for definitive avian and/or mammalian field studies. The Agency can provide guidance for developing such studies.

b. Definitive field study, which is a multiyear, multilocation study to quantify the effects of the particular use, in this case, exposed avian species. This would involve studying several species with various censusing and population measuring techniques for several years to determine the extent of effects that have already been demonstrated in preliminary type studies and incident reports.

Aquatic Studies

Aquatic mesocosm studies are required for the identified sites because of concern for hazard to aquatic organism and fish. Aquatic mesocosm studies are field studies incorporating multiple treatment ponds of similar size and characteristics and multiple treatment rates. Effects to the aquatic community will be determined by measuring the difference in success and development of biota in treatment ponds to control ponds.

Site Cat.	Use Site	Use	Type of Field Study Required
A	(TERRESTRIAL FOOD)		
	Pastures	Mosquito and other pest control	Preliminary mammalian study Definitive avian study Aquatic mesocosm study
B	(TERRESTRIAL NONFOOD)		
	Nonagricultural areas	Mosquito control	Preliminary mammalian study Definitive avian study Aquatic mesocosm study
	Manmade structures	Bird control	Preliminary avian study

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

Site Cat.	Use Site	Use	Type of Field Study Required
C	(AQUATIC FOOD)		
	Rice	Mosquito control	Preliminary avian study Aquatic mesocosm study
D	(AQUATIC NONFOOD)		
	Standing water	Mosquito control	Preliminary mammalian study Definitive avian study Aquatic mesocosm study
		All granular formulations	Preliminary avian study
I	(INDOOR)		
	Livestock	Pest control	Preliminary avain study Aquatic mesocosm study
G	(FORESTRY)		
	Nonagricultrual areas including forest	Mosquito control	Preliminary mammal study Definitive avian study Aquatic mesocosm study

The registrant may arrange to meet with Agency staff to discuss approaches to addressing the concerns for terrestrial wildlife and aquatic biota and the possibility of designing studies that may cover multiple-use sites for mosquito control. Protocols for each required study must be submitted within 6 months following receipt of this Registration Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

19/Required to support registration of those formulations that are applied directly on cattle or swine because livestock may be expected to move into waterways after being treated. Also, a test with either a coldwater or warmwater species is required to support manufacturing-use products used to make indoor formulations.

20/All studies were conducted with either a 46% or 47.5% ai formulation. The inerts were not identified.

21/Formulation testing is required of all nongranular formulations that are applied directly to water. Formulations of similar percent active ingredient and similar inerts/other actives may be represented by one such formulation. The following are the nongranular formulations applied directly to water. Testing one representative formulation from each group is acceptable.

Group	Registration No.	Formulation	Use Site
1	5011-74	2.5% RTU	Aquatic nonfood
1	5011-92	1.0% RTU	Aquatic nonfood
1	10088-18	1.0% RTU	Aquatic nonfood
2	400-226	1.0% Dust	Aquatic nonfood
3	3125-73	25.3% EC*	Aquatic nonfood
3	904-384	25.0% SC/L	Aquatic nonfood
4	3125-148	9.67 lb/gal**	Aquatic food (rice)

*Also identified in Listing of Registered Pesticide Products as 4 lb/gal, Confidential Statement of Formula indicated that this is a 50.9% ai formulation. In either case, it still may be represented by, or represent, group 3.

**If this formulation is greater than 90% active ingredient, it does not need to be tested as a formulated product.

22/Field testing indicated that fish were killed by an application to water that should not have caused concentrations lethal to fish. It is possible that a degradate is more toxic than fenthion. Acute tests with either a coldwater or a warmwater species must be conducted using major degradates (see footnote No. 1).

23/Reserved pending results of freshwater fish tests using major degradates of fenthion (see footnote No. 1).

24/Partially fulfills requirement for estuarine fish test; fulfills requirement for shrimp test.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

[25]/Partially fulfills requirement for estuarine fish test; fulfills requirement for shrimp and oyster tests.

[26]/Estuarine fish 96-hour test required.

[27]/Fish early life stage and aquatic invertebrate life cycle test required because uses involve multiple applications.

[28]/May be required depending on results of other tests because multiple applications/treatments permitted.

[29]/Required unless the fish accumulation test, normally required under Section 158.290 Environmental Fate, is provided.

[30]/The available field tests do not fulfill the requirements for quantitative field studies with aquatic and estuarine organisms.

[31]/Because of the potential for treated livestock to enter and contaminate ponds, rivers, and streams, residue monitoring is required. This involves choosing at least eight sites where cattle are being treated and where these cattle can move into a natural waterway. Waterways must be representative of those used by cattle, including large ponds, streams, and rivers. Treatment must be at maximum label rates; number of animals treated must be typical of large-scale farming operations. Within 6 hours after treatment, cattle must be herded into the waterway that is to be sampled. Waterway must be at least 5 feet deep and cattle must be permitted to move about freely once they enter the water. Water must be sampled as soon as cattle enter and sampling must continue for at least 1 month. Samples in rivers or streams must also be collected at several stations downstream, as well as at the point where the cattle are wading. Samples in ponds must be from pond center as well as in shallower parts. The registrant(s) must submit a protocol for this monitoring program within 6 months from the date of this standard.

[32]/Required to support registration of those formulations used to control mosquitoes and formulations registered for use on ornamentals.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes (cont'd)
Sec. 158.540 Plant Protection Testing - Footnotes (cont'd)

33/Studies to determine persistence of fenthion and major degradates on livestock. This would include field residue monitoring of material collected from the back of treated livestock. Material to be sampled should include hair pulled (not cut) from the treated area, and insects that may be present. This material should be analyzed for fenthion and its major degradates or metabolites. Sampling should be collected daily for the first week, and then weekly for at least 100 days. A treated cow and pig should be sacrificed to determine residues in various parts of their body at various times (0-day, 1 week, and 1 month) following treatment. These parts should include back skin, various internal organs, fat, and muscle. The purpose of these studies is to identify the degradates/metabolites present in various materials associated with livestock treatment, and to determine the levels of these chemicals and their persistence.

34/Basic toxicity testing on freshwater bivalves and their glochidia. This would involve testing freshwater species that would be indicative of endangered mussels. The Agency is requesting additional guidance from the Fish and Wildlife Service on how these tests should be designed. Registrants are encourage to submit a protocol before initiating any testing.

35/Basic toxicity tests on reptiles and amphibians. All amphibian lifestages should be studied. The tested species should be representative of endangered species that could be exposed to fenthion. The Agency is requesting further guidance from the Fish and Wildlife Service on how these test should be designed and recommends that registrants submit protocols before initiating the tests.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
Sec. 158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honeybee Acute Contact Toxicity	TGAI	A B	Yes	00036935	No	---
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	A B	No		Yes[2]/	15 Months
141-4 - Honeybee Subacute Feeding Study	Reserved[3]/	- -	-		-	---
141-5 - Field Testing for Pollinators	TEP	A B	No		No[4]/	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[5]/	- -	-		-	---
142-2 - Aquatic Insect Life-cycle Study	Reserved[5]/	- -	-		-	---
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[5]/	- -	-		-	---
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3 -	Reserved[5]/	- -	-		-	---

TABLE A
GENERIC DATA REQUIREMENTS FOR FENTHION

Sec. 158.590 Nontarget Insects - Footnotes

[1]/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Data Call-In Letter dated April 29, 1986.

[2]/Residual toxicity data are required because data from the acute test indicate high toxicity.

[3]/Reserved pending development of test methodology.

[4]/Data reviewed to date do not indicate the need for field testing.

[5]/Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Part 158, Subpart C, Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	Yes	40085801	Reserved[3]/,[4]/	03/21/87
61-2 - Description of Starting Materials and Manufacturing Process	MP	All	Yes	40085801	Reserved[3]/,[5]/	03/21/87
61-3 - Discussion of Formation of Impurities	MP	All	Yes	40085801	Reserved[3]/.[6]/	03/21/87
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All	No		Yes[7]/	09/22/87
62-2 - Certification of Ingredient Limits	MP	All	No		Yes[8]/	09/22/87
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No		Yes[9]/	09/22/87
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No		Yes[10]/	03/21/87
63-3 - Physical State	MP	All	Yes	40085802	Reserved[3]/,[10]/	03/21/87

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Part 158, Subpart C, Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-4 - Odor	MP	All	No		Yes[10]/	03/21/87
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	Yes	40085802	Reserved[3]/,[10]/	03/21/87
63-12 - pH	MP	All	No		Yes[11]/	03/21/87
63-14 - Oxidizing or Reducing Action	MP	All	No		Yes[12]/	03/21/87
63-15 - Flammability	MP	All	No		Yes[13]/	03/21/87
63-16 - Explodability	MP	All	No		Yes[14]/	03/21/87
63-17 - Storage Stability	MP	All	Yes	40085802	Reserved[3]/,[10]/	12/21/87
63-18 - Viscosity	MP	All	Yes	40085802	Reserved[3]/,[15]/	03/21/87
63-19 - Miscibility	MP	All	No		Yes[10]/[16]/	9 Months
63-20 - Corrosion Characteristics	MP	All	Yes	40085802	Reserved[3]/,[10]/	12/21/87
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No[17]/	------

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Part 158, Subpart C, Product Chemistry - Footnotes

1/ Test Substance: MP - Manufacturing-Use Product (Formulation intermediates (FI) are also included in the category of manufacturing-use products). The 95% (EPA Reg. No. 11556-36),93% EC (EPA Reg. No. 3125-148), 93% (EPA Reg. No. 3125-197), 10% FI (EPA Reg. Nn. 655-371) amd 20% FI (EPA Reg. No. 655-372) are considered MPs.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Comprehensive Data Call-In letter dated April 29, 1986.

3/ Data submitted in response to the April 29, 1986 Comprehensive Data Call-In letter were not received in time to be included in the data base reviewed for this standard. Therefore no determination has been made as to the adequacy of this data in satisfying the data requirement. Should the data be found unacceptable after Agency review a new study is required under Section 3(c)(2)(B) of FIFRA.

4/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

5/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of starting materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each starting material must be provided, along with information regarding the properties of those materials.

6/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the starting materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

7/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Part 158, Subpart C, Product Chemistry - Footnotes (continued)

[8]/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at >0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

[9]/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

[10]/ Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[11]/ Data required if the test substance is dispersible in water.

[12]/ Data required if the product contains an oxidizing or reducing agent.

[13]/ Data required if the product contains combustible liquids.

[14]/ Data required if the product is potentially explosive.

[15]/ Data required if the product is a liquid.

[16]/ Data required if the product is a liquid and is to be diluted with petroleum solvents.

[17]/ If samples are needed, the Agency will request them.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	A B C D G I	Yes	00132312 40186704	Reserved[3]/	06/19/87
81-2 - Acute Dermal - Rat	MP	A B C D G I	Yes	00132314 40186705	Reserved[3]/	06/19/87
81-3 - Acute Inhalation - Rat	MP	A B C D G I	Yes	00132317 40186706 40186707	Reserved[3]/	06/19/87
81-4 - Eye Irritation - Rabbit	MP	A B C D G I	Yes	00132319 40186708	Reserved[3]/	06/19/87
81-5 - Dermal Irritation - Rabbit	MP	A B C D G I	Yes	00132319 40186709	Reserved[3]/	06/19/87
81-6 - Dermal Sensitization - Guinea Pig	MP	A B C D E	Yes	40186710	Reserved[3]/	06/19/87
81-7 - Acute Delayed Neurotoxicity - Hen	MP	A B C D E	Yes	40229201	Reserved[3]/	09/22/87

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENTHION

Sec. 158.340 Toxicology - Footnotes

1/ Test material: MP = Manufacturing-Use Product (Formulation intermediates are also included in the category of manufacturing-use products).

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated by calendar dates determined from the date of issuance of the Agency's Comprehensive Data Data Call-In letter dated April 29, 1986.

3/ If at the conclusion of the Agency's review the data is found unacceptable a new study will be required under Section 3(c)(2)(B) of FIFRA.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container.
[40 CFR 162.10(f)]

SUMMARY-2

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

SUMMARY-3

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. **You may label** the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, SIOR, PEST/DIS, and CONI/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

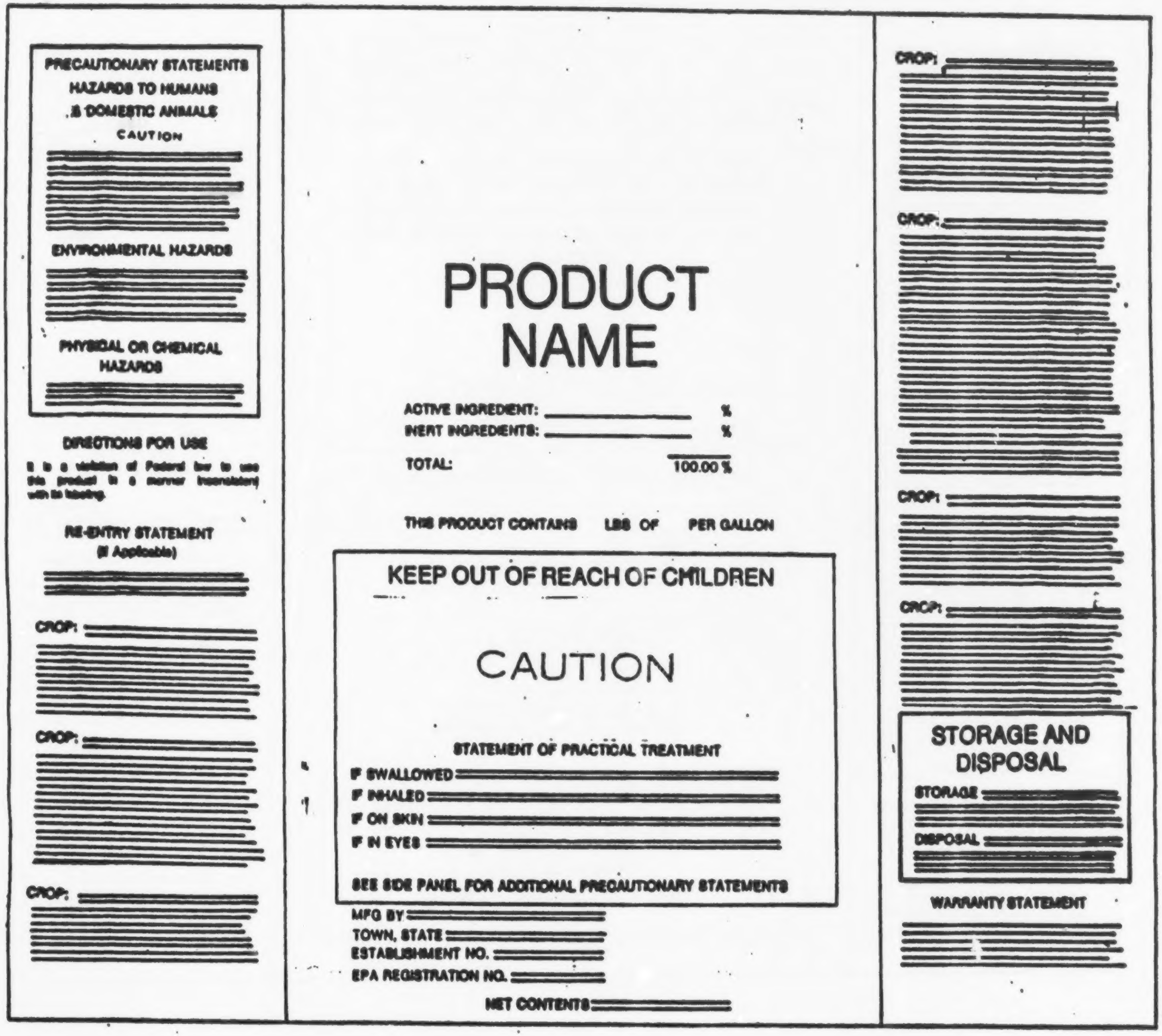
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS: ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED ____
IF INHALED ____
IF ON SKIN ____
IF IN EYES ____

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY ____
TOWN, STATE ____
ESTABLISHMENT NO. ____
EPA REGISTRATION NO. ____

NET CONTENTS ____

CROP:

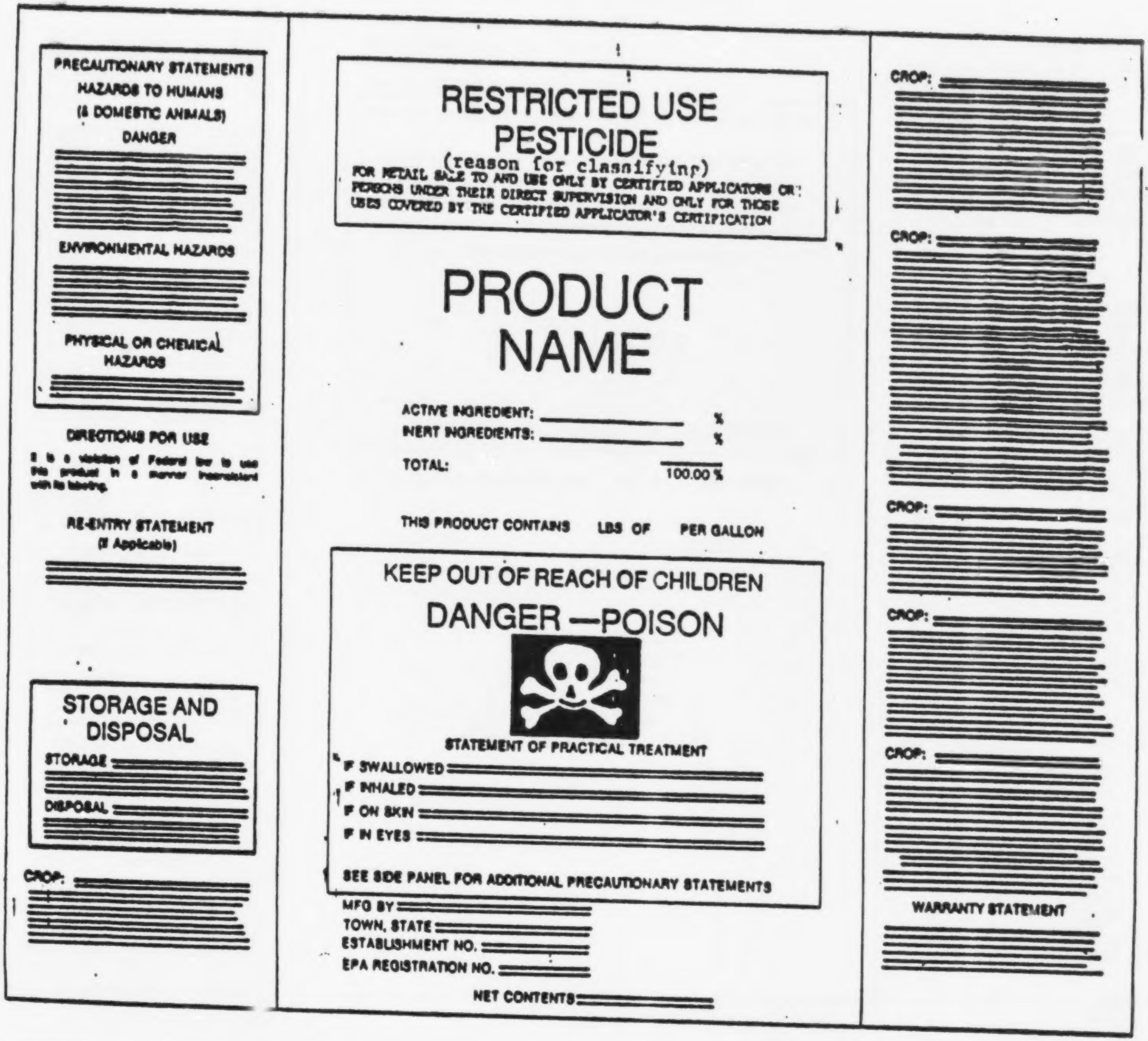
CROP:

CROP:

CROP:

STORAGE AND DISPOSAL
STORAGE ____
DISPOSAL ____

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ____________ %
INERT INGREDIENTS: ____________ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

(e) *Conditional registration.* Any application for which a review of scientific data is needed, other than an application which the Agency determines may be considered for unconditional registration under paragraph (d) of this section, will be treated as an application for conditional registration under FIFRA sec. 3(c)(7) and will be reviewed and acted upon as set forth in §§ 162.160 through 162.177.

(f) *Denial of registration.* The Administrator shall deny an application reviewed under paragraph (d) of this section if any of the requirements of paragraph (d)(2) of this section are not met, or if there are insufficient data to make the required determinations.

(1) *Notification.* Promptly after making a determination to deny a registration, the Administrator shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.

(2) *Opportunity for remedy by applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.

(ii) The applicant may petition the Administrator to withdraw his application. The Adminstrator may, in his discretion, deny any petition for withdrawal and proceed to issue a notice of denial in accordance with paragraph (f)(3) of this section.

(3) FEDERAL REGISTER *publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly issue in the FEDERAL REGISTER a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.

(4) *Hearing rights.* Within 30 days following publication of the denial in the FEDERAL REGISTER, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of this chapter. If no hearing is timely requested, the denial shall become effective at the end of the 30 days.

(g) *Disposition of material submitted with the application.* The test data and other information submitted with an application shall become a part of the official file of the Agency for that application or registration. Except as provided by section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.

[48 FR 34004, July 26, 1983]

§ 162.8 Data to be furnished by applicant.

(a) An applicant for registration, reregistration, or amendment of a registration under FIFRA sec. 3(c)(5) shall furnish data as required by the Agency to determine whether his application may be approved under this Part.

(b) An applicant shall submit with his application any factual information regarding adverse effects of the pesticide on the environment or man that:

(1) Has been obtained by him or has come to his attention; and

(2) Insofar as he is aware, has not previously been submitted to the Agency.

Such information shall include, but shall not be limited to, published or unpublished laboratory studies and accident experience.

[48 FR 34005, July 26, 1983]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a)-(b) [Reserved]~~

~~(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified~~

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

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[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

IV. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00062094	Chemagro (1976) ⌊Residues of Fenthion in Swine Tissue⌋: Report No. 36071. (Compilation; unpublished study including report no. 48661, received Aug 2, 1977 under 11556-37; submitted by Bayvet, Shawnee Mission, Kans.; CDL:230979-I)
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00081115	Loser, E.; Lorke, ? (1969) Bay 29493: Generation Tests on Rats: Report No. 1400; 25761. (Unpublished study received May 11, 1971 under 11556-1; prepared by Farbenfabriken Bayer AG, West Germany, submitted by Bayvet, Shawnee Mission, Kans.; CDL: 100920-AA)
00081363	Doull, J.; Root, M.; Cowan, J.; et al. (1963) Chronic Oral Toxicity of Bayer 29493 to Male and Female Dogs: Submitter 10853. (Unpublished study received Mar 19, 1963 under 3125-73; prepared by Univ. of Chicago, Depts. of Pharmacology and Pathology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:051134-BH)
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V. FORMS APPENDICES

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

Form Approved. OMB No. 2070-0057. Expires 11-30-89.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PA Form 8580-6 (10-82)

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date______________________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Sec. 158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.____________________ Date____________________

Guidance Document for______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Sec. 158.120 PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ____________ concerning a requirement for submission of "generic" data on the active ingredient ______________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ___________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ________________________________
(Signature

Dated: ____________________ ________________________________
(Typed)

EPA Form 8570-27